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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,066	05/06/2005	Jong-Soo Woo	Q87744	2761

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EXAMINER	
ROBERTS, LEZAH	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/534,066	WOO ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 06 May 2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a water-insoluble anti-cold drug.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

A water-insoluble anti-cold drug selected from: acetaminophen, ibuprofen, S-ibuprofen, dextromethorphan hydrobromide, noscapine hydrochloride, trimetoquinol hydrochloride, guaifenesin, d-chlorpheniramine maleate, carbetapentane citrate, tipepidine citrate, cloperastine hydrochloride, cloperastine fendizoate, tipepidine hibenzate, d,l-

methylephedrine hydrochloride, ephedrine hydrochloride, phenylephedrine hydrochloride, pseudoephedrine hydrochloride, phylpropanolamine and a mixture thereof.

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the anti-cold drug are divergent in structure. For example, noscapine is a multi-ring structure comprising a fused ring system, whereas drugs such as ibuprofen and acetaminophen one aromatic ring. The anti-cold drugs recited by the claims may also be used or listed as other types of drugs such as anti-inflammatory drugs as in the case of ibuprofen, a anti-tussive in the case of noscapine and anti-pyretic in the case of acetaminophen.

During a telephone conversation with Sunhee Lee on June 7, 2006 a provisional election was made with traverse to prosecute the invention comprising ibuprofen as the anti-cold drug. Affirmation of the election of an anti-cold drug must be made by applicant in replying to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement filed May 6, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all

other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claims

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US 2002/0032171).

Chen et al. teach clear oil-containing pharmaceutical compositions. The compositions are pre-concentrated and when water is added, the compositions form a clear dispersion. The compositions comprise a triglyceride, a therapeutic agent and a carrier comprising at least two surfactants. The therapeutic agents that may be delivered by the compositions include ibuprofen (col. 30, line 17), encompassing claim 2. Surfactants include propylene glycol fatty acid esters (paragraph 0069, also encompassing claim 6), polyoxyethylene sorbitan fatty acid esters; polyoxyethylene-polyoxypropylene block copolymers; polyoxyethylene hydrogenated vegetable oils; and mixtures thereof (paragraph 0108), encompassing claim 5. Triglycerides include vegetable oils, animal fats, and fatty acid triglycerides, encompassing claim 6. Solubilizers may also be used in the compositions to increase the solubility of the pharmaceutical active ingredient or other composition components and may be removed by distillation or evaporation. Preferred solubilizers include ethanol, which has a boiling point of 78.4°C.[1], which encompasses claim 4. The amount of solubilizer that can be included in the compositions is not particularly limited but may range up to 400% based on the weight of the surfactant. The pre-concentrate is prepared by stirring the

[1] Wikipeidia, the free encyclopedia, page 1, properties.

surfactants and triglyceride together to form a homogeneous mixture. The therapeutic agent is added and stirred until solubilized. Solubilizers may also be added to the compositions. In regards to claims 7 and 10, Table 21 shows different ratios of the triglycerides and surfactants that encompass the instant claims for the surfactant/oil ratio. The solubilizer or co-surfactant is based upon the surfactant and is also encompassed by the claims. The amounts of the drugs used vary from composition to composition (Table 25). The claims also use the symbol for about in the ratios. The term "about" (or in this case the symbol about) permits some tolerance. See, for example, In re Ayers, 69 USPQ 109 (CCPA 1946), where "at least about 10%" was held to be anticipated by a teaching of a content "not to exceed about 8%." The reference differs from the instant claims insofar as it does not teach a specific order for mixing the pre-concentrate compositions when using a co-surfactant (solubilizer) or the specific ratios for the compositions comprising anti-cold drugs, such as ibuprofen.

Selection of any order of mixing ingredients is *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). The reference discloses a way of making the pre-concentrate compositions wherein the end result is the active agent being dissolved in a solubilizer such as ethanol, and the ethanol being removed. It would have been obvious to one of ordinary skill in the art to have dissolved the drug first followed by adding the other components of the composition motivated by the desire to ensure the drug was fully dissolved and the homogeneous mixture made by the surfactant and triglyceride solution was maintained, as supported by case law.

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also *In re Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 (Fed. Cir. 2003). ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages"). Since the ethanol co-surfactant has a boiling point of 78.4°C, it would have been obvious to one of ordinary skill in the art to have evaporated the ethanol co-surfactant at a temperature between 50°C and 100°C, as supported by cited precedent. It would also have been obvious to one of ordinary skill in the art to have adjusted the ratios to the desired ranges motivated by the desire to obtain optimal conditions for the particular drug being used as supported by the reference and cited precedent.

2) Claims 1-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (US 6,458,373).

Lambert et al. teach emulsion vehicles for poorly soluble drugs. The compositions comprise tocopherol oil (encompassing claim 6), a surfactant and an active agent. The active agents include ibuprofen (Example 24), which encompasses claim 2. The active agent may be dissolved in a solvent such as ethanol, which

encompasses claims 3-4. The ethanol is removed after the addition of tocopherol. A surfactant is then added to the compositions. Surfactants include polyethylene glycol and poloxamers, encompassing claim 5. A pre-emulsion is made with the addition of surfactant and buffer to the active agent and tocopherol. Another method disclosed by the reference comprises dissolving the active agent, oil and surfactants in ethanol at a temperature ranging from 40 to 45°C and removing the ethanol by vacuum. The particle size of the microparticles made when the pre-emulsion is added to water ranges from 10 to 500 nm encompassing claim 11. In one example an active agent was dissolved in ethanol followed by the addition of the oil and surfactant. The ethanol was then removed by vacuum (Example 27). The reference differs from the instant claims insofar as it does not specifically the drug being dissolved in the ethanol to make homogeneous drug solution.

Selection of any order of mixing ingredients is *prima facie* obvious. *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). The reference discloses different ways of making the pre-emulsion compositions wherein the active agent is being dissolved in a composition comprising a co-surfactant such as ethanol, and the ethanol being removed. It would have been obvious to one of ordinary skill in the art to have dissolved the drug first followed by adding the other components of the composition motivated by the desire to ensure the drug was fully dissolved. It would also have been obvious to one of ordinary skill in the art to have adjusted the ratios to the desired ranges motivated by the desire to obtained optimal conditions for the particular drug being used as supported by cited precedent (see Obviousness rejection 1).

Claims 1-11 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts

Frederick Krass

Patent Examiner
Art Unit 1614

Primary Examiner
Art Unit 1614